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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/585,718

01/09/2007

Carl T Brighton

UPN-4914

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23377 7590 10/01/2009
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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

10/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/585,718 | BRIGHTON, CARL T | |
| | Examiner | Art Unit | |
| | James S. Ketter | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-13, 16-26, 29 and 31 is/are allowed.
- 6) ☒ Claim(s) 27, 28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/5/09; 4/9/09; 8/25/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-13, 16-26, 29 and 31 are allowed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Brighton et al. (cited in previous Office Action), for reasons of record set forth in the previous Office Action.

Claim is drawn to a method of up-regulating the gene expression of at least one of bone morphogenetic protein-4, 5, 6, and 7 (BMP-4, BMP-5, BMP-6, and BMP-7, respectively) in targeted tissue, comprising the steps of: generating at least one specific and selective signal having a frequency from 30 kHz to 120 kHz that when applied to a field generating device operatively disposed with respect to said targeted tissue causes the generation of a field having an amplitude of about 2 to 40 mV/cm in the targeted tissue that is specific and selective for the up-regulation of the gene expression of BMP-4, BMP-5, BMP-6, and/or BMP-7 in said targeted tissue as measured by mRNA when said field is applied to the targeted tissue containing said BMP-4, BMP-5, BMP-6, and/or BMP-7; and exposing the targeted tissue to the specific and selective field generated by said field generating device upon application of said at least one specific and selective signal thereto for a predetermined duration of time at a predetermined duty cycle from approximately 10% - 100% so as to selectively up-regulate the gene expression of

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BMP-4, BMP-5, BMP-6, and/or BMP-7 in said targeted tissue as measured by mRNA. Claim 28 is drawn to a method for treating at least one of a bone fracture, fracture at risk, delayed union, nonunion, bone defect, spine fusion, osteonecrosis, and osteoporosis, comprising the steps of: generating at least one specific and selective signal having a frequency of 30 kHz to 120 kHz that when applied to a field generating device operatively disposed with respect to targeted tissue causes the generation of a field having an amplitude of about 2 to 40 mV/cm in the targeted tissue that is specific and selective for the up-regulation of at least one of the gene expression of bone morphogenetic protein-4, 5, 6, and 7 (BMP-4, BMP-5, BMP-6, and BMP-7, respectively) in said targeted tissue as measured by mRNA when said field is applied to the targeted tissue containing said BMP-4, BMP-5, BMP-6, and/or BMP-7; and exposing the targeted tissue to the specific and selective field generated by said field generating device upon application of said at least one specific and selective signal thereto for a predetermined duration of time at a predetermined duty cycle from approximately 10% - 100% so as to selectively up-regulate the gene expression of BMP-4, BMP-5, BMP-6, and/or BMP-7 in said targeted tissue as measured by mRNA. Claim 30 recites a method of treating at least one of bone fractures, fractures at risk, delayed unions, nonunions, bone defects, spine fusion, osteonecrosis, and osteoporosis comprising the steps of exposing bone tissue to the specific and selective field generated by the device of claim 29 so as to up-regulate gene expression of BMP-4, BMP-5, BMP-6, and/or BMP-7 as measured by mRNA in the bone tissue.

The instant claims recite bone morphogenetic proteins BMP-4 through BMP-7.

However, application number 10/257,126, which matured into US Patent 7,465,566, only

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discloses BMP-2, and thus does not support the instant claims. As such, priority to 10/257,126 is not accorded, and an effective filing date of 11 January 2005 is granted for the instant claims.

Brighton et al. teaches, e.g., at the Abstract, methods and devices for the regulation of gene expression by cells via the application of specific and selective electric and electromagnetic signals so as to target diseased or injured tissue for treatment. At page 15, in the description of Figure 4, it is taught that aggrecan mRNA production in articular cartilage chondrocytes is stimulated by an electric field of 60 kHz at 20mV/cm, using capacitive coupling at various duty cycles. A duty cycle of 1 minute on/7 minutes off (12.5%) over 30 cycles produced a greater production of aggrecan mRNA than the control. At page 19, first full paragraph, it is taught that BMP-2 gene may be stimulated by the disclosed methods and devices.

The conditions taught by Brighton et al. for aggrecan and other genes overlaps considerably, i.e., many of the embodiments are the same, with the conditions recited in the instant claims for BMPs. These conditions thus would have been expected to have stimulated BMP expression along with aggrecan (or the other genes disclosed in Brighton et al. using such overlapping conditions for expression). As such, these overlapping conditions would have anticipated the invention of the instant claims.

At page 11 of the amendment filed 18 May 2009, Applicant argues that there is a lack of support for BMP-4 through BMP-7 in the reference, as only BMP-2 was discussed, and the cited genes would not obviously have had similar regulation. However, as noted above, the conditions taught in the reference would have met the claim limitations regardless of whether one of ordinary skill would have predicted so or not.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK

1 October 2009

/James S. Ketter/

Primary Examiner, Art Unit 1636